

## **REMARKS**

Claims 1-27 were and remain pending. By this Amendment, claims 1, 3, 4, 13, 14, and 21 are amended. Reconsideration and allowance in view of the above amendments and following remarks is earnestly solicited.

### **IDS**

The Office Action noted that WO 98/52633 was not considered on the ground that a copy was not filed with the August 22, 2005 IDS or the copy was not legible. *See* 5/27/09 Office Action, ¶ 1. Applicants respectfully dispute the Office Action's assertion. The IDS included a legible copy of WO 98/52633, as confirmed by the application's Image File Wrapper on PAIR (PAIR date 8/22/2005). Moreover, the reference includes an English abstract on its cover sheet. Applicants therefore submit that their submission of WO 98/52633 was in full compliance with all rules, and respectfully requests the Examiner to consider this reference and confirm such consideration by initialing it on Applicants' August 22, 2005 PTO/SB/08.

### **Non-Statutory Subject Matter Rejection**

Claim 1 was rejected under 35 U.S.C. § 101 as being directed toward non-statutory subject matter, specifically "an abstract idea which can be performed by mental processing." 5/27/09 Office Action, ¶ 2. Applicants respectfully traverse this rejection for the following reasons.

First, claim 1 recites "detecting the commencement of inhalation via a sensor." Such detection is not merely a mental step, but rather is the measurement/detection of a real world event, i.e., inhalation by a person. Moreover, Applicants have amended claim 1 to explicitly recite that such detection is "via a sensor." The recites use of such a sensor confirms that the claim is not merely a mental step, but rather involves the use of a structural sensor. Moreover, Applicants have amended claim 1 to include an additional detecting step, specifically, "detecting a time the person takes to stop inhaling after being signalled." This additional detection step is likewise the measurement/detection of a real world event, i.e., a time the person takes to stop inhaling after being signaled. Such detection of a real world action is statutory subject matter, not a mere mental step.

Second, claim 1 also recites “signalling to the person to cease inhalation.” Such signalling is likewise not merely a mental step, but rather involves creating some type of signal cognizable by the person (e.g., audible sound, visual display). Such signalling involves a physical transformation that is itself statutory subject matter.

For at least these reasons, Applicants submit that claim 1 is directed toward statutory subject matter, and respectfully request the withdrawal of this § 101 rejection.

Applicants also specifically traverse this rejection to the extent that it applies to various of claim 1’s dependent claims. For example, claim 18 recites, among other things, “delivering an aerosolized substance into at least a part of the inhaled airstream,” which involves a physical transformation, not merely a mental step.

#### **Indefiniteness Rejections**

Claims 1-20 and 27 were rejected under 35 U.S.C. § 112, ¶ 2, as indefinite. Applicants respectfully traverse this rejection as follows.

Claim 1 was rejected as indefinite on the ground that there is insufficient antecedent basis for the recitation “the time the person takes to stop....” 5/27/09 Office Action, § 3. Applicants have amended claim 1 to additionally recite “detecting a time the person takes to stop inhaling after being signaled,” which provides proper antecedent basis for the recitation “the time the person takes to stop....” Applicants therefore respectfully request the withdrawal of this rejection.

Claim 1 was also rejected as indefinite on the ground that “it is not clear which disclosed structure is being used to perform the claimed steps such as the controller/microprocessor.” 5/27/09 Office Action, § 3. Applicants traverse this rejection because claim 1 does not specify or limit what structure is being used to perform all of the claimed steps. Nor are Applicants required to so limit claim 1, and claim 1 remains definite even without such limitations. The breadth of claim 1 should not be confused with indefiniteness. Applicants therefore respectfully request the withdrawal of this indefiniteness rejection.

Claim 3 was rejected as indefinite on the ground that there is insufficient antecedent basis for the recitation “the first pre-set period of time.” 5/27/09 Office Action, § 3. Applicants have

amended this phrase by deleting the term “first.” The amended term “the pre-set period of time” has proper antecedent basis in base independent claim 1. Applicants therefore respectfully request the withdrawal of this indefiniteness rejection.

Claim 14 was rejected as indefinite on the ground that there is insufficient antecedent basis for the recitation “the I:E ratio.” 5/27/09 Office Action, § 3. Applicants have amended this phrase to use the article “a” rather than the article “the.” Applicants therefore respectfully request the withdrawal of this indefiniteness rejection.

#### **Anticipation Rejection Over Edgar**

Claims 21 and 23-25 were rejected under 35 U.S.C. § 102(b) as anticipated by Edgar (U.S. Patent No. 4,677,975). Applicants respectfully traverse this rejection as applied to independent claim 21 for the following reasons.

First, amended claim 21 recites, among other things, that “the controller is configured to ... detect, via the airflow sensor, a time the person takes to stop inhaling after being signaled.” In the Edgar device, “the start of inhalation is detected by the ... flow sensor 14.” Edgar, col. 3, lines 6-8. However, Edgar’s device does not use the flow sensor 14 to detect a stop to the inhalation. Accordingly, the controller in Edgar’s device is not “configured to ... detect, via the airflow sensor, a time the person takes to stop inhaling after being signaled,” as recited in claim 21. Nor would it have been obvious to modify Edgar to detect the stop to the inhalation because there was no obvious reason to have done so.

Second, claim 21 recites, among other things, that “the controller is configured to ... adjust the pre-set period of time for subsequent inhalations depending on the detected time the person takes to stop inhaling after being signaled.” Because Edgar does not even detect this “detected time,” as explained above, Edgar does not disclose adjustment of the pre-set period or time based on a non-disclosed, non-obvious “detected time.” Indeed, Edgar does not disclose any ability whatsoever to adjust the pre-set period of time. Nor would it have been obvious to modify Edgar’s controller to “adjust the pre-set period of time for subsequent inhalations depending on the detected time the person takes to stop inhaling after being signaled,” as recited in claim 21, because there was no obvious reason to have done so.

For at least these reasons, Applicants respectfully request the withdrawal of the anticipation rejection of claim 21, as well as its dependent claims, which are allowable at least because they depend from patentable claim 21.

**Obviousness Rejection Over Schuster in view of Mishelevich and Crockford**

Claims 1-12, 18-20, and 27 were rejected under 35 U.S.C. § 103(a) as obvious over Schuster (U.S. Patent No. 5,906,202) in view of Mishelevich (U.S. Patent No. 5,363,842) and Crockford (U.S. Patent Application Publication No. 2003/0205229). Applicants respectfully traverse this rejection as applied to independent claim 1 for the following reasons.

First, claim 1 recites, among other things, “detecting a time the person takes to stop inhaling after being signaled.” None of the cited references, either individually or in combination, disclose such a combination of recitations. Although Schuster discloses “prompt[ing] the patient to stop the inhalation,” Schuster does not disclose the detection of how long it takes the patient to comply. Schuster, col. 2, line 63. Mishelevich and Crockford are similarly deficient.

Second, claim 1 recites, among other things, “adjusting the pre-set period of time for subsequent inhalations.” The Office Action concedes that Schuster lacks such a teaching. The Office Action similarly concedes that modifying Schuster in view of Mishelevich likewise lacks such a teaching because Mishelevich merely discloses “direct[ing] the patient to change breathing pattern to match the pre-set time period instead of changing the pre-set time period.” 5/27/09 Office Action, ¶ 7. The Office Action asserts that Crockford would have made it obvious to have adjusted the pre-set period of time “in order to accommodate to a patient’s breathing pattern who may have respiratory problems and cannot change their breathing pattern” based on Crockford’s alleged disclosure of “adjust[ing] subsequent breathing patterns to match the patient’s needs (Crockford para. 0056 ln. 9-15).” 5/27/09 Office Action, ¶ 7. To the contrary, Crockford has no such teaching. Crockford does not teach adjusting the patient’s breathing pattern at all, and is merely directed toward adjusting internal workings of the drug delivery device itself. The cited passage from Crockford merely discloses changing the timing of atomization within the device so as to occur “during a part of the inhalation of the patient.”

Crockford, ¶ [0056]. Such internal workings of Crockford's device have nothing to do with changes to how Crockford's device instructs the patient to breath. Thus, Crockford does not make it obvious to "adjust[] the pre-set period of time for subsequent inhalations," wherein the pre-set period is used to "signal[] to the person to cease inhalation," as recited in claim 1.

Third, claim 1 recites, among other things, "adjusting the pre-set period of time for subsequent inhalations depending on the time the person takes to stop inhaling after being signaled." None of the cited references, nor their combination, disclose such a combination of recitations because, as explained above, they do not even render obvious the detection of such a "time the person takes to stop inhaling after being signaled." Accordingly, the cited references cannot render obvious using such a non-disclosed, non-obvious "time the person takes to stop inhaling after being signaled" as the basis for "adjusting the pre-set period of time," as recited in claim 1.

The Office Action asserts that the combination would render it obvious "to adjust[] the pre-set time...in order to accommodate to a patient's breathing pattern who may have respiratory problems and cannot change their breathing pattern." 5/27/09 Office Action. Even if such an assertion were correct (Applicants dispute this as explained above), Applicants specifically traverse the Office Action's further assertion that such accommodation for the patient's respiratory problems/breathing cycle "would depend on the time the person takes to stop inhaling after the signaled [sic] to stop as comparison to target envelopes." 5/27/09 Office Action, p. 6, ¶ 7. Quite to the contrary, adjustment to accommodate for the specific breathing cycle of a patient does not necessarily or obviously depend on the time the person takes to stop inhaling after any signal to stop inhalation is given. A patient's respiratory-problem-based breathing cycle has nothing to do with a lag between when the patient is signaled to stop inhalation and when the patient actually does so. Thus, none of the references, nor their combination disclose or otherwise render it obvious to adjust the pre-set time based on a patient's compliance lag, i.e., "the time the person takes to stop inhaling after being signaled."

For at least these reasons, Applicants respectfully request the withdrawal of this obviousness rejection of claim 1, as well as its dependent claims, which are allowable at least because they depend from patentable claim 1.

**Obviousness Rejection Over Schuster in view of Mishelevich, Crockford, and Krumbiegel**

Claim 13 was rejected under 35 U.S.C. § 103(a) as obvious over Schuster in view of Mishelevich, Crockford, and Krumbiegel (U.S. Patent No. 5,928,156). Applicants respectfully traverse this rejection at least because claim 13 depends from claim 1, and claim 1 is patentable over Schuster in view of Mishelevich and Crockford as explained above. Krumbiegel does not cure any of those deficiencies with respect to claim 1. Applicants therefore respectfully request the withdrawal of this obviousness rejection.

**Obviousness Rejection Over Schuster in view of Mishelevich, Crockford, Krumbiegel, and Strom**

Claims 14-17 were rejected under 35 U.S.C. § 103(a) as obvious over Schuster in view of Mishelevich, Crockford, Krumbiegel, and Strom (U.S. Patent No. 6,240,920). Applicants respectfully traverse this rejection at least because claims 14-17 depend from claim 1, and claim 1 is patentable over Schuster in view of Mishelevich and Crockford as explained above. Krumbiegel and Strom do not cure any of those deficiencies with respect to claim 1. Applicants therefore respectfully request the withdrawal of this obviousness rejection.

**Obviousness Rejection Over Edgar in view of Reinhold**

Claim 22 was rejected under 35 U.S.C. § 103(a) as obvious over Edgar in view of Reinhold (U.S. Patent No. 7,073,499). Applicants respectfully traverse this rejection at least because claim 22 depends from claim 21, and claim 21 is patentable over Edgar as explained above. Reinhold does not cure any of Edgar's deficiencies with respect to claim 21. Applicants therefore respectfully request the withdrawal of this obviousness rejection.

**Obviousness Rejection Over Edgar in view of Schuster**

Claim 26 was rejected under 35 U.S.C. § 103(a) as obvious over Edgar in view of Schuster. Applicants respectfully traverse this rejection at least because claim 26 depends from claim 21, and claim 21 is patentable over Edgar as explained above. Schuster does not cure any

of those deficiencies with respect to claim 21. Applicants therefore respectfully request the withdrawal of this obviousness rejection.

### Conclusion

To the extent that Applicants have not separately addressed each rejection of each dependent claim, this is not to be construed as an admission of the correctness of that rejection. Rather, Applicants believe that the independent claims are patentably distinguishable over the cited references for the reasons noted above, so that the rejection of one or more of the dependent claims need not be addressed at this time. Applicants reserve the right to address the rejection of any dependent claim at a later time should that become warranted.

Applicants submit that the present application is in condition for allowance, and earnestly solicit an early notification to that effect.

Should there be any questions or concerns regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Please charge any fees associated with the submission of this paper to Deposit Account Number 50-0558. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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